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10/511,710	11/02/2005	Andrea E Dunaif	NWESTERN-09656	6732

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,710	DUNAIF, ANDREA E	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 15 October 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Remark

No IDS has been filed to date of the instant Office Communication.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 is drawn to a method of determining the presence or the absence of polycystic ovary syndrome (herein, "PCOS").

Claim 3 is dependent from claim 1, drawn to a method of treating a polycystic ovary syndrome.

A method of determining the presence of absence of PCOS, is a diagnosis method.

Hence, a method of treatment as recited in claim 3 is outside of the metes and bounds of the diagnosis method of claim 1, thereby failing to further limit the parent claim.

In Pfizer Inc. v. Ranbaxy (79 USPQ2d 1583, CAFC 2006), U.S. Patent No. 5,273,995 (herein, '995 patent) was invalidated, wherein claim 6 failed to further limit the parent claim 2.

In '995 patent, claims 1, 2, and 6 were drawn to the following (the names of the Compounds are omitted for the sake of brevity):

Claim 1. Compound A or Compound B; or pharmaceutically acceptable salts thereof.

Claim 2. Compound of claim 1, which is Compound A.

Claim 6. The hemicalcium salt of the compound of claim 2.

The court found that since claim 2, by its limitation excluded Compound B as well as all pharmaceutically acceptable salts therefore (by limiting only Compound A), claim 6 which was drawn to its hemicalcium salt was an improper dependent form for failing to further limit the previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to recite a final process step, which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a ***positive, active fashion***. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, claim 1 is drawn to a method to determine the presence or absence of polycystic ovary syndrome in an individual, yet the claim recites a final step assessing the DNA or RNA for the presence of PCOS-associated allele A8(+) of a base pair polymorphism designated D19S884.

While limitation recited in the phrase, "the absence of the allele indicates likely..." appears to recite the correlation of the assessment with the conclusion of PCOS diagnosis, the limitation is preceded by the word, "wherein," which does not confer that such step be "active and positive."

For example, the active steps of the claimed method is only in the assessment of the allele A8(+) of a base pair polymorphism in D19S884.

Hence, the claims do not set forth the conditions/state when the method has been completed [i.e., needs to agree with preamble].

Claims 2 and 3 are indefinite by way of their dependency on claim 1.

Claims 1-3 are indefinite for the recitation of the term, "allele A8" because without a specific description (i.e., by sequence) of what is considered to be a particular type of an allele, the term does not properly identify what it is.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in In Re Wands (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

Breadth of the Claims and Enablement Issues:

The breadth of claims 1 and 2 is broadly drawn to a method of determining the presence of the absence of PCOS in an individual, wherein the presence of a particular allele (allele 8) of

D19S884 implicates said individual with the presence of a PCOS causative gene in the genome of said individual. Allele 8 is not defined by its structure, in the claims nor in the specification, but rather, only by its name.

The breadth of claim 3 relies on the initial diagnosis made by claim 1.

The enablement issue arises because the claims do not particularly describe structurally what is considered to be allele 8 of D19S884, so as to allow a skilled artisan to practice the invention without undue experimentation.

It is the position of the Office that the claims nor the specification reasonably allow a skilled artisan to determine what is considered to be allele 8 of D19S884, thereby failing to enable said skilled artisan to practice the invention as claimed without undue experimentation.

Amount of Guidance & Working examples:

The specification appears to give some guidance to a skilled artisan in that the allele 8 of D19S884 appears to have some statistical significance in association with PCOS (see Figure 2, pages 46-48).

However, the specification is absolutely silent in disclosing what form of D19S884 is considered to be allele 8.

State of Prior Art & Unpredictability:

Villuendas et al. (Fertility and Sterility, January 2003, vol. 79, no. 1, pages 219-220) disclose that from a total of 216 alleles of D19S884 found in PCOS individuals (from Spain and Italy), none of the alleles had any statistical significance in associating these D19S884 alleles to PCOS (page 220, Table 1).

As can be seen, without an explicit description of what is considered to be D19S884 A(8), it is impossible to determine whether any of the 216 alleles identified by Villuendas et al. includes the allele which the instant application is reciting as allele 8.

This point is even conceded by one of Applicant's papers (The Journal of Clinical Endocrinology & Metabolism, 2005, vol. 90, no. 12, pages 6623-6629), wherein Applicant states that, "Tucci *et al.* (22) tested 10 of the STRs we described (20) for association with PCOS in a group of 85 Caucasian PCOS patients and 87 age-matched Caucasian control women; they found evidence for association only with D19S884 (P=0.006). (In this and other published studies, ***because the number of CA repeats in the associated alleles was not given, it is not clear whether the associated alleles is the same as the one we reported, now known to contain 17 CA repeats***." (page 6623, 2nd column, bottom paragraph through page 6624, 1st column, 1st paragraph).

Skill Level:

The skilled level of the artisan is deemed high.

Conclusion:

Since the instant specification is entirely insufficient in guiding a skilled artisan to determine what is considered to be D19S884 A(8), and coupled with the evidence which demonstrates the presence of hundreds of alleles found for D19S884 in PCOS experiencing subjects, one of skill in the art would not be able to practice the invention as claimed without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

> subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Urbanek et al. (PNAS, July 1999, vol. 96, pages 8573-8578).

Urbanek et al. disclose reagents which target D19S884 (page 8574, 1st column, 3rd paragraph), which is associated with PCOS.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagent compositions of Urbanek et al. into a kit in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Since claim 4 does not set forth any structure possessed by the reagent which is responsible for detecting the presence or absence of PCOS associated allele of D19S884, the reagents disclosed by Urbanek et al. would necessarily be capable of being used for identifying D19S884.

With regard to the limitation drawn to an instruction for the correlation, such is deemed a non-functional descriptive material which does not confer patentable weight.

In *In re Ngai*, 70 USPQ 2d 1862 (CAFC 2004) the court, referencing *In re Gulak*, 703 F.2d 1381 (Fed. Cirl. 1983), held that addition of a new set of instructions into a known kit does ***not*** interrelate with the kit in the same way as the numbers interrelate with the kit in the same way as the numbers interrelated with the band (as in *Gulak*). The court held that the printed matter in no way depends on the kit, and the kit does not depend on the printed matter expressing that if a patent were to be granted solely on the presence of a different printed instructions, "anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product,"

concluding that a known product by simply attaching a set of instructions to that product would not be entitled a new patent.

Therefore, the invention as claimed is *prima facie* obvious over the cited reference.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the

status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Primary Examiner
Art Unit 1637
9/29/2006

YOUNG J. KIM
PRIMARY EXAMINER

YJK